Prospera®

PRO-II®

NPWT System by DeRoyal®

PROSPERA® PRO-II® NPWT System

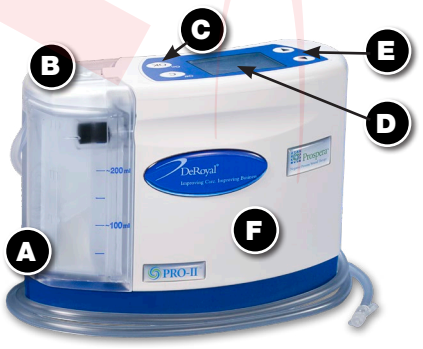
Patient & Caregiver Quick Reference Guide

WARNING: To avoid **SERIOUS OR FATAL INJURY**, read and understand all physician instructions, and labeling of this device. This prescription device is for use under the direction and supervision of a clinician. **THIS GUIDE IS A SUPPLEMENTAL DOCUMENT. CONTACT YOUR HEALTHCARE PROVIDER FOR ANY QUESTIONS OR CONCERNS. IF YOU CANNOT REACH YOUR PROVIDER OR IF IT IS A MEDICAL EMERGENCY, CALL 911.**

CAUTION Use only DeRoyal® brand kits, canisters, and accessories with this PROSPERA® PRO-II® device to enable continuous and safe operation.

DISPLAY SYMBOLS

	Battery full
	Battery low
	Battery empty
	Up
	Down
OK	OK (On, Enter)
C	Cancel (Off, Back)
	Device is connected to external power source.
	Max pressure / Max time
	Min pressure / Min time
	Keylock (symbol in display) activated automatically during operation.
	Filter run time elapsed; replacement of the internal filter by an authorized DeRoyal service technician is required.
X/Y	Alarm display settings



A Disposable exudate canister (250 cc canister shown) with integrated therapy tube

B Canister locking mechanism

C OK and C buttons

D Display

E ▼ and ▲ arrow buttons

F PRO-II® device

Battery Alarms

The Battery Alarm triggers when device needs to be charged. Immediately connect device to external power source.

To Charge Device

1. Plug jack end of power cord into port on bottom of the device.
2. Plug pronged connector into external power outlet. Green LED will illuminate when connected properly.
3. When connected properly, the plug icon will appear on the display screen.

The PROSPERA® device should be charged daily with the DeRoyal provided power supply.

When in use, place the device upright on a secure surface, avoiding areas where device is prone to falling or being damaged.

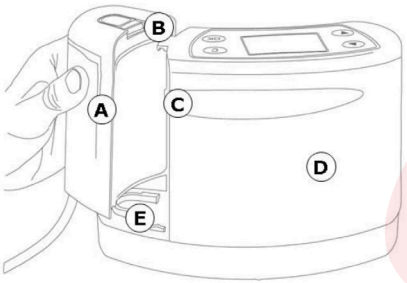
Powering Off

A patient or caregiver should never power off the device.

If therapy stops or device powers down, contact your heathcare provider or medical equipment provider immediately.

Canister Exchange

Initiate canister changes only when Canister Full alarm is actived and therapy is paused. Confirm canisters and accessories are within arms reach prior to beginning any canister change procedures. Inspect all canisters for damage or defects. Replace the canister if it is damaged.



A Disposable exudate canister including therapy tube

B Locking mechanism for canister

C Aspiration port

D PRO-II® device

E Guiding rail

REPLACEMENT OF THE DISPOSABLE CANISTER OF THE PRO-II DEVICE

1. Ensure the PRO-II device is not actively providing therapy.
2. Clamp tubing using the blue clamp.
3. Separate the therapy tubing from the canister tubing and close the canister connector with the protective cap.
4. Press on the “Push Here” button on the top of the canister (B) and keep it pressed while pulling the disposable exudate canister horizontally away from the device.
5. Dispose of the disposable exudate canister and the integrated therapy tubing as directed by your healthcare provider.
6. Connect a new disposable exudate canister to the device. Ensure that the disposable exudate canister is properly attached to the device.
7. Connect the therapy tubing to the canister tubing.
8. Unclamp dressing tubing.
9. Press (OK) to start therapy.

Monitor wound exudate in canister for signs of excess blood loss or other complications. If active bleeding occurs, clamp dressing, apply pressure, and disconnect from canister. Contact your health care provider or local emergency service (dial 911 within US) immediately.

Carry Bag

1. Disconnect device from external power supply
2. Confirm the battery life is sufficient to provide therapy for your travels
3. Confirm remaining canister volume is adequate for your needs
4. Open the carry bag hook and loop and place on a stable and flat surface
5. Carefully place the device in the Carry Bag using care not to invert the device
6. Place quick reference guide & power plug inside side pocket
7. Close hook and loop. Ensure canister tubing is not kinked or bent
8. Adjust strap as needed for comfort

DeRoyal recommends the device be kept out of the Carry Bag anytime the patient is not mobile and the device may be safely placed on a stable and flat surface.

DeRoyal® NPWT Dressing Kits

The Pro-II device is designed to operate safely and effectively using only DeRoyal® Propel negative pressure dressing kits. A normal compressed dressing should appear shrunk, similar to a raisin, compacted or vacuumed. It may feel slightly hard. This is a sign the NPWT is working. If the dressing has lost its vacuumed appearance therapy may be interrupted. See page 8 for trouble shooting dressing seals. If unable to find the problem area and/or the alarms do not sound, call your home care nurse or healthcare provider for instruction.

Do not discard any unused kits or packaging (including shipping boxes) unless directed to by your equipment provider or a trained clinician.

Dressing changes should be performed by trained clinicians, following physicians prescribed treatment. Improper use or inadequate training may result in serious injury to the patient.

CAUTION: The patient or caregiver should routinely check the system, including wound dressings, canister and device display (pressure, alarms, battery life, etc.) at least every eight (8) hours. Look for a compressed appearance at dressing surface. A compressed appearance means dressing is properly adhered to the skin, the dressing dome has properly adhered to the dressing, and negative pressure is active.

Contact your clinician if you see signs of infection. These may include: redness, pain, warmth, swelling at or near your wound or changes in your wound's odor or discharge. Clinical care is necessary to diagnose or treat infection.

Display screen and status by color:

Green
System states
Device is providing appropriate therapy

Yellow
Caution screen.
Device requires action.
Device is idle or needs to be plugged in

Red
System states error alarm, therapy is being interrupted

An error message can read as: System Open, System Closed, Check Dressing Seal, Battery Low, Battery Empty, or Re-start pump. Contact your healthcare provider for assistance with an alarm.

Contact your healthcare provider with any medical questions or concerns. If you can not reach your healthcare provider for any reason, contact your local emergency services at "911."

Intended Use

The Propsera PRO-II device is indicated for patients that would benefit from a therapy device particularly as the device may promote wound healing by removal of wound exudate, debris, and infectious material or for the aspiration and removal of surgical fluids, tissue (including bone), gases, bodily fluids or infectious material from the patient's airway or respiratory support system. These devices may be used during surgery.

Indications/Contraindications

The PROSPERA® PRO-II® Negative Pressure Therapy System is a prescription medical device for use under instruction of a licensed and trained clinician.

CONTRAINDICATIONS

- Necrotic tissue with eschar present
- Unexplored or non-enteric fistulas
- Untreated osteomyelitis
- Wounds containing malignant tissue
- Exposed anastomotic site
- Exposed arteries, nerves – including vagus nerve – blood vessels, veins, internal organs

The PROSPERA® PRO-II® Negative Pressure Wound Therapy (NPWT) System is a prescription medical device. Read and understand all warnings, cautions, and instructions completely and carefully before use. Using accessories, canisters or spare parts other than those recommended by and sold from DeRoyal® may compromise the safety and function of the device. Use of NPWT can cause complications, exacerbate existing conditions or cause serious or fatal injury when used on patients with certain co-morbidities. **IF THERAPY IS DISCONTINUED OR DISRUPTED FOR MORE THAN TWO HOURS, SEEK EMERGENCY MEDICAL ATTENTION.**

Local wound care by NPWT cannot overcome the deficits of unrelieved malnutrition, pressure, trauma, or compromised blood flow. Follow all instruction and interventions as directed by a health care provider to reduce or relieve factors contributing to impaired wound healing in order to achieve optimum outcomes.

In case of an emergency, contact your local emergency service immediately (Dial 911 within the US).

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Troubleshooting Guide

Alarm Message	Device Status	Potential Alarm Origin	Action
ERROR System Open	Therapy automatically puased	Disposable exudate canister not connected or improperly connected	Check connections between canister-device and canister-tubing
Check Dressing Seal	Attempting to provide therapy	Dressing has major opening; dressing film does not adhere to skin	Check dressing seal for leaks or creases
ERROR System Closed	Therapy automatically paused	Exudate flow obstructed (clamp/cap closed, tubing kinked, stenosis in tubing)	Check clamps, caps and all tubing and tubing connections. Ensure tubing is not kinked.
		Disposable exudate canister full	Replace disposable exudate canister; Restart Therapy
		Alarm triggered when canister not connected, filter is blocked	Contact equipment provider
ERROR Battery Empty or Battery Low	Device powering off imminent.	Battery nearly depleted	Connect device to external power source
ERROR Re-start Pump	Therapy is Off	Device turned on, but therapy not started.	Contact HCP or equipment provider
		Device not turned off at end of use	
ERROR Internal Error	Status unknown	Device damaged from drop or other unknown event	Do not use device; contact equipment provider

If any of the troubleshooting methods do not solve the problem, immediately call your home care nurse or health care provider. If you are unable to contact your home care nurse or health care provider, IMMEDIATELY CALL 911 and/or go to the nearest Hospital.